

REMARKS

Claim Rejections – 35 U.S.C. § 103

Claims 1-7, 10-12, 16-23, 29-31, 33, 34, 43, 53, 58-61 and 63 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,217,578 to Crozet et al. (hereafter “Crozet”) in view of U.S. Patent No. 5,545,167 to Lin (hereafter “Lin”); claims 8 and 9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of U.S. Patent Publication No. 2003/0114853 to Burgess et al. (hereafter “Burgess”); claims 13-15, 24-28, 37 and 38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of U.S. Patent No. 5,976,135 to Sherman et al. (hereafter “Sherman”); claims 35, 36, 54, 55 and 57 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of U.S. Patent No. 6,554,832 to Shluzas (hereafter “Shluzas”); claims 39-42, 44, 45, 49, 51 and 52 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of Shluzas and in further view of U.S. Patent No. 6,273,914 to Papas (hereafter “Papas”); claim 62 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of U.S. Patent No. 7,137,986 to Troxell et al. (hereafter “Troxell”); and claim 46 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin in further view of Papas and in further view of U.S. Patent No. 5,702,393 to Pfaifer (hereafter “Pfaifer”).

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. See, Manual of Patent Examining Procedure (MPEP) §2141. While performing this analysis, the cited references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. See, MPEP §2141.02 (citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). From

these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness.

Additionally, the Supreme Court in the recent decision of KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

KSR, 82 USPQ2d at 1396. For at least the following reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established in this case.

Claim Amendments

Independent claim 44 has been amended to recite further features associated with the claimed invention. Claim 45, which depends from independent claim 44, has also been amended to recite further features associated with the claimed invention. Claims 46, 53 and 58 have been amended to address various informalities.

Arguments in Support of Patentability

Independent Claim 1 and Dependent Claims 2-31, 33-42 and 59-63

As indicated above, independent claim 1 stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 1 recites, in combination with other features and elements:

an interconnection element including a first body and a stud, said first body having a first aperture formed therein and said stud extending from the body, said first aperture including an upper portion formed having a lobed shape; a first rod connector including a first shaft terminating in a first rod engaging portion and a lobe extending laterally from an end of said first shaft and displaced axially along said first shaft from the first rod engaging portion, said first shaft and said lobe slideably received within the first aperture such that said lobe passes through said first aperture and upon rotation of said first rod connector said lobe prevents said first rod connector from being removed from said first aperture.

For at least the reasons that follow, it is respectfully submitted that independent claim 1 is patentable over the cited references.

The outstanding Office Action asserts that Crozet discloses all the features of independent claim 1 except for a first shaft and lobe being slideably received within a first aperture such that the lobe passes through the first aperture and upon rotation of the first rod connector the lobe prevents the first rod connector from being removed from the first aperture. (See e.g., Office Action, page 6). However, in an attempt to overcome this deficiency, the Office Action cites Lin and asserts that it would have been obvious “to have substituted the fastening mechanism of Crozet et al. with a fastening mechanism as taught by Lin in order to achieve the predictable result of preventing a shaft from being removed from an aperture.” (See Office Action, page 7, lines 10-12). As will be discussed in greater detail below, the proposed logic in support of the suggested modification of Crozet is flawed. Moreover, those skilled in the art would not modify Crozet in the manner set forth in the Office Action.

Crozet discloses a cross connector 10 that includes a first rod gripping element 18 and a second rod gripping element 20 that are interconnected by a pivot element 44. The pivot element 44 is positioned on an arm 28 that extends laterally from the first rod gripping element 18. More particularly, Crozet discloses at column 5, line 55 to column 6, line 3:

[p]ivot element 44 may be permanently assembled onto arm 28 during manufacture. This permanent mounting is accomplished by placing pivot element 44 on the arm and forming a flange 62 at the free end of arm 28 and then permanently attach the arm to the body of the first gripping element. Flange 62 maybe formed by upsetting the material at the free end of the arm. The diameter of upset portion 62 is larger than the opening in pivot element 44 formed by combined circular bores 58 and 60. Thus, while pivot element 44 is freely slidable on arm 28, it cannot become disengaged.

Alternatively, the end of arm 28 may be threaded into a bore in rod gripping element 18 in which case the pivot element is placed on arm 28 prior to being threaded into element 18. The flange 62 will still keep the pivot element 44 from disengaging. This procedure can be done at the time of use.

Thus, Crozet clearly discloses an arrangement where a shaft is prevented from being removed from an aperture. Indeed, the Office Action even acknowledges that Crozet discloses this type of arrangement. (See page 7, lines 3-5). Given this arrangement, those skilled in the art would clearly have no reason to, and indeed would not, substitute the fastening mechanism of Crozet

with the fastening mechanism of Lin in order to achieve a result that is already clearly performed by the arrangement of Crozet. As a corollary, the rationale required by KSR for modifying Crozet in the manner suggested is missing.

In addition to the foregoing, it is respectfully submitted that Crozet also teaches away from the proposed modification which includes the fastening mechanism of Lin. More particularly, Crozet discloses, at column 4, lines 9-18:

The first rod gripping element, the second rod gripping element, and the clamping element may be held loosely together by a stop on the end of the arm or rod. The stop maybe made by upsetting the material at the end of the arm, thus forming a diameter greater than the larger first diameter of the bore in the head to thereby prevent the head from disengaging from the arm once assembled. The lock nut can be placed loosely on the threaded portion of the pivot element, thereby allowing relative motion but preventing the unintentional disassembly of the cross connector.

Thus, the combination of flange 62 and lock nut 52 provide a provisional locking of the cross connector 10 where the first and second rod gripping elements 18, 20 are movable relative to one another to facilitate adjustments to the cross connector 10 as it is positioned relative to spinal rods 12 and 14. As illustrated and disclosed in Lin, the retaining bolt 200 is axially fixed relative to connection element 300 once it is engaged with fastening nut 400. Indeed, upon only a ninety degree rotation of fastening nut 400 relative to retaining bolt 200, the connection assembly disclosed by Lin becomes locked. (See e.g., Lin, column 3, lines 64-67 and column 4, lines 10-16). As a result, the connection assembly of Lin fails to provide any provisional locking where the elements, such as retaining bolt 200 and connection element 300, remain movable relative to one another. Likewise, those skilled in the art would be lead away from and would not employ the fastening mechanism of Lin in the Crozet device since doing the same would eliminate the ability to adjust the positioning of the components of the cross connector 10 when the components are provisionally assembled together.

For at least the reasons set forth above, the Applicant submits that independent claim 1 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 1 and allowance of the same. Claims 2-31, 33-42 and 59-63 depend either directly or indirectly from independent claim 1 and are submitted to

be patentable for at least the reasons supporting the patentability of independent base claim 1, although further reasons support the patentability of these claims.

For example, claim 8 recites “wherein the first shaft is curved so as to be non-linear,” while claim 9 depends from claim 8 and further specifies that the second shaft is curved. The Office Action acknowledges that these features are not disclosed by the Crozet/Lin combination, but cites Burgess and asserts that it would have been obvious to use curved shafts “in order to achieve the predictable result of extending between and connecting rod engaging portions of the device to one another, which in turn connects spinal rods to one another.” (See Office Action, page 8). The Applicant respectfully submits that this rationale is flawed. Notably, the cross connector 10 of Crozet already achieves the result identified by the Office Action without using curved shafts. Likewise, the rationale required by KSR is missing and those skilled in the art would not have modified Crozet to include curved shafts as asserted by the Office Action. Claim 11, which recites “wherein the first shaft and the second shaft are curved,” is further patentable over the cited references for at least these reasons as well.

Claim 24 specifies that the assembly of claim 1 further comprises “a washer carried by the stud and positioned in the second body of the second rod connecting member, wherein engagement of the fastener to the stud urges the washer to contact the first shaft of the first rod connecting member and clamp the first rod connecting member in a first orientation relative to the second rod connecting member.” The Office Action suggests that the combination of Crozet, Lin and Sherman discloses this arrangement. However, the Applicant notes that none of these references disclose a washer positioned in the body of a second rod connecting member. For example, with respect to Sherman, washer 55 is not positioned within a body of a second rod connecting member. Accordingly, the subject matter of claim 24, as a whole, has not been accounted for, and withdrawal of the rejection of claim 24 is respectfully requested. Claims 25-28 further depend from claim 24 and are further patentable for at least the reasons supporting the further patentability of claim 24.

Claim 39 recites that the assembly of claim 1 further comprises an insert disposed within the second aperture, and that the insert is configured to at least partially encircle the stud. The Office Action acknowledges that the Crozet/Lin combination fails to disclose this feature. However, citing Papas, the Office Action asserts that it would have been obvious to construct the

connection mechanism of Crozet in view of Lin with a connection mechanism as taught by Papas. (See Office Action, page 11). With particular regard to Papas, the Office Action indicates that it discloses “an insert (Fig. 2, ref. 96) at least partially encircling a stud (Fig. 2, ref. 72) and a fastener engaged with the stud (Fig. 2, ref. 18).” The Applicant respectfully submits that Papas fails to disclose an insert as suggested by the Office Action. Indeed, Papas discloses that reference numeral 96 refers to a spherical ball that defines the second end 38 of link 12. (See, Papas, column 7, lines 25-26). As clearly illustrated in Figure 1 of Papas, link 12 extends between adjacent vertebrae and does not define an insert. Accordingly, the subject matter of claim 39, as a whole, has not been accounted for, and claim 39 is further patentable over the cited references.

Claim 60 recites “wherein said stud has a longitudinal axis, and said first shaft has a longitudinal axis, and said stud longitudinal axis is oblique to said first shaft longitudinal axis.” The Office Action indicates that the Crozet/Lin combination discloses these features. However, it is respectfully submitted that Crozet and Lin both fail to disclose this arrangement of features. For example, as illustrated in Figures 2, 3, 4A and 4B of Crozet, the axis 42 of pivot element 44 extends perpendicularly, and not obliquely, to axis 64 of the arm 28. Accordingly, it is respectfully submitted that claim 60 is also patentable over the cited references.

As another example, claim 62 recites:

wherein said interconnection element includes a pair of flanges extending outwardly diametrically opposite each other circumferentially about an external surface of said first body, and said second body includes a pair of internal flanges in said second aperture, wherein said flanges of said interconnection element allow said flanges of said second body to pass through gaps between said flanges of said interconnection element during assembly and upon rotation of said second body said flanges of said interconnection element engage said flanges of said second body.

The Office Action acknowledges that the Crozet/Lin combination fails to disclose these features. However, Troxell is advanced for disclosing an interconnection element that comprises flanges that extend into an aperture in order to lock the components together. (See Office Action, page 12). Even assuming arguendo that Troxell could somehow be construed to disclose these features, the Applicant notes that Troxell still fails to disclose a second body that includes a pair of internal flanges in an aperture, as recited in claim 62. Accordingly, the subject matter of claim

62 has not been accounted for in the Office Action, and claim 62 is further patentable over the cited references.

Independent Claim 43

Independent claim 43 also stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 43 is directed to a method that includes, among other features, “interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1.” Likewise, it is respectfully submitted that independent claim 43 is patentable over the cited references for at least the reasons set forth above in support of the patentability of independent claim 1. Accordingly, withdrawal of this rejection and allowance of claim 43 are respectfully requested.

Independent Claim 44 and Dependent Claims 45, 46, 49 and 51

As indicated above, independent claim 44 stands rejected as being unpatentable over Crozet in view of Lin in further view of Shluzas in further view of Papas. Independent claim 44 has been amended and now recites, in combination with other features and elements:

an insert positioned over said stud having a lower surface configured to engage the first shaft of the first rod connecting member extending through the third aperture and an upper portion positioned in said first aperture of said second body; and a fastener extending through the first aperture of the second body and into an internal recess of the insert to fixedly engage the stud thereby securing the orientation of the first rod connector relative to the second rod connector.

Support for the amendment to independent claim 44 may be found, for example, on page 17, lines 28-30 of the written description of the subject application. For at least the reasons that follow, it is respectfully submitted that independent claim 44 is patentable over the cited references.

As an initial matter, for reasons similar to those discussed above with respect to claim 39, Papas fails to disclose the insert recited in independent claim 44. Moreover, the Crozet/Lin/Shluzas/Papas combination also fails to disclose a fastener that extends through a first aperture of a second body and into an internal recess of an insert to fixedly engage the stud and secure the orientation between a first rod connector relative to a second rod connector, as recited

in independent claim 44. More particularly, Crozet discloses a lock nut 52 that engages with external surface 34 of bearing portion 32 of the second rod gripping element 20. (See e.g., Crozet, column 7, lines 3-6). Lin discloses a fastening nut 400 which engages against the external surface of a washer 500. Shluzas discloses a fastener 58 that does not extend through a first aperture of a second body as those elements are otherwise arranged in independent claim 44, and that also does not extend into any internal recess of ball 48. Rather, Shluzas discloses that fastener 58 engages and clamps against rod 42. (See e.g., Shluzas, column 2, lines 43-56). With respect to Papas, this reference discloses a nut 18 which, as illustrated Figure 2 for example, engages against the external surface of a washer 19. (See also, Papas, column 6, lines 59-62). Likewise, none of the cited references disclose a fastener that is positioned according to the arrangement specified in independent claim 44. As a corollary, the subject matter of independent claim 44 as a whole has not been accounted for, and a *prima facie* case of obviousness has therefore not been established.

For at least the reasons set forth above, the Applicant submits that independent claim 44 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 44 and allowance of the same.

Claims 45, 46, 49 and 51 depend either directly or indirectly from independent claim 44 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 44, although further reasons support the patentability of these claims. For example, claim 45 has been amended and now recites “wherein the insert includes a slit along a vertical axis, said slit extending between and opening at opposite ends of said insert.” Support for the amendment to claim 45 may be found, for example, in Figure 14b and the accompanying text of the subject application. None of the cited references discloses an insert that includes a slit, as now recited in claim 45. Indeed, with respect to Shluzas, the ball 48 includes tabs that are defined by slots that only open at one end of ball 48.

Independent Claim 52

Independent claim 52 also stands rejected as being unpatentable over the Crozet/Lin/Shluzas/Papas combination. Claim 52 is directed to a method that includes, among other features, “interconnecting the first spinal rod to the second spinal rod using the assembly of

claim 44.” Likewise, it is respectfully submitted that independent claim 52 is patentable over the cited references for at least the reasons supporting patentability of independent claim 44.

Accordingly, withdrawal of this rejection and allowance of independent claim 52 are respectfully requested.

Independent Claim 53 and Dependent Claims 54, 55 and 57

As indicated above, independent claim 53 stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 53 recites, in combination with other features and elements:

said projection being able to move through said aperture when said shaft is in a first orientation with respect to said aperture, and being unable to move through said aperture when said shaft is in a second orientation with respect to said aperture different from said first orientation and a single fastener to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other.

For at least the reasons that follow, it is respectfully submitted that independent claim 53 is patentable over the cited references.

The Office Action asserts that Crozet discloses all the features of claim 53 except for “a projection being able to move through said aperture when said shaft is in a first orientation with respect to said aperture, and being unable to move through said aperture when said shaft is in a second orientation with respect to said aperture different from said first orientation.” (See Office Action, paragraph spanning pages 6-7). However, as indicated above with respect to independent claim 1, the Office Action attempts to overcome this deficiency by citing Lin and asserting that it would have been obvious “. . . to have substituted the fastening mechanism of Crozet et al. with a fastening mechanism as taught by Lin in order to achieve the predictable result of preventing a shaft from being removed from an aperture.” (See Office Action, page 7, lines 10-12).

As discussed above with respect to independent claim 1, the rationale required by KSR for modifying Crozet to include the fastening mechanism of Lin is missing. Moreover, as also discussed above with respect to independent claim 1, those skilled in the art would be lead away from modifying Crozet in the manner suggested by the Office Action since doing so would eliminate the ability to adjust the positioning of the components of the cross connector 10 when

the components are provisionally assembled together. Additionally, even assuming arguendo that Crozet could somehow be modified to include the fastening mechanism of Lin, the Applicant notes that the resulting device would not include a single fastener to secure the first and second spinal rod connectors to each other, as recited in independent claim 53. Notably, the fastening mechanism of Lin includes a pair of fastener components (i.e., washer 500 and fastening nut 400). As a corollary, even if Crozet were modified as proposed, the subject matter of independent claim 53, as a whole, would not be accounted for.

For at least the reasons set forth above, the Applicant submits that independent claim 53 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 53 and allowance of the same. Claims 54, 55 and 57 depend either directly or indirectly from independent claim 53 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 53.

Independent Claim 58

Independent claim 58 also stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 58 is directed to a method that includes, among other features, “interconnecting the first spinal rod to the second spinal rod using the apparatus of claim 53.” Likewise, it is respectfully submitted that independent claim 58 is patentable over the cited references for at least the reasons supporting patentability of independent claim 53. Accordingly, withdrawal of this rejection and allowance of claim 58 are respectfully requested.

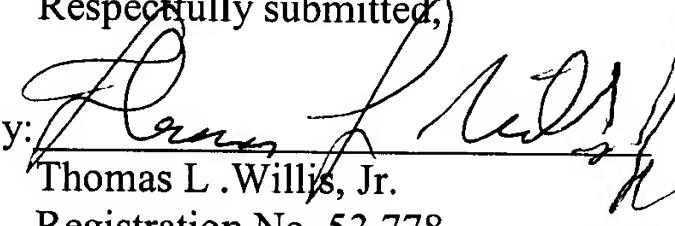
CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the subject application is now in condition for allowance with pending claims 1-31, 33-46, 49, 51-55 and 57-63.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By:


Thomas L. Willis, Jr.
Registration No. 53,778

Date: June 17, 2009
Medtronic
2600 Sofamor Danek Drive
Memphis, TN 38132
Telephone: 901-396-3133
Facsimile: 901-399-3040